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APR 30 2008

510(k) Summary

As Required by 21 CFR 807.92

The Assigned 510(k) Number is: K073614

Submitter Information:

Manufacturer Name:
Foosin Medical Supplies Inc., Ltd.
No.312, Shichang Road
Weihai, Shandong, China, 264209

Contact Person of the Submission:
Ms. Diana Hong
Mr. Eric Chen
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongxin Zhongshan Mansion,
No.19, Lane 999, Zhong Shan Nan Er Road
Shanghai, China 20020
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eric.chen@mid-link.net

Applicant Device Information

1. Absorbable Polyglycolic Acid Suture with Needle

1.1 Applicant Device Information

Trade/Proprietary Name: WG-Surgical Sutures with Needle
Common Name: Absorbable Polyglycolic Acid Suture with Needle
Classification Name: Suture, Absorbable, Synthetic, Polyglycolic Acid
Device Class: II
Product Code: GAM
Regulation Number: 878.4493
Review Panel: General & Plastic Surgery

Intended Use:

Absorbable polyglycolic acid suture with needle is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic, cardiovascular and neurological tissues.

1.2Predicate Device

K-number: K063536

1.3Device Description

The applicant devices of absorbable polyglycolic acid suture with needle consist of a polyglycolic acid surgical suture made of polyglycolic acid and a stainless steel needle. It is braided. It is EO sterilized, and prygon-free.

1.4 Performance Data:

Physical testing was performed on the subject device to USP 30, including <861> Suture Diameter, <871> Suture Attachment, <881> Tensile Strength. Biocompatibility studies were performed in accordance with ISO10993. In vivo strength test was also conducted on the subject device to demonstrate rates of tensile and mass loss.

1.5 Substantially Equivalence Determination

The applicant device of Absorbable Polyglycolic Acid Suture with Needle is substantially equivalent to the predicate device.

2. Absorbable Polyglycolic Acid Suture with Needle

2.1Applicant Device Information

Trade/Proprietary Name: WG-Surgical Sutures with Needle
Common Name: Absorbable Polydioxanone Suture with Needle
Classification Name: Suture, Absorbable, Synthetic, Polydioxanone
Device Class: II
Product Code: NEW
Regulation Number: 878.4840
Review Panel: General & Plastic Surgery
Intended Use:

Absorbable Polydioxanone Suture with Needle is indicated for use in all types of soft tissue approximation, including use in cardiovascular tissue where growth is expected to occur, PDO suture is not indicated in adult cardiovascular tissue, microsurgery, ophthalmic and neural tissue.

2.2Predicate Device

K-number: K053380

2.3Device Description

The applicant devices of absorbable polydioxanone suture with needle consist of a polydioxanone surgical suture made of polyester and a stainless steel needle. It is unbraided. It is EO sterilized, and prygon-free.

2.4 Performance Data:

Physical testing was performed on the subject device to USP 30, including <861> Suture Diameter, <871> Suture Attachment, <881> Tensile Strength. Biocompatibility studies were performed in accordance with ISO10993. In vivo strength test was also conducted on the subject device to demonstrate rates of tensile and mass loss.

2.5 Substantially Equivalence Determination

The applicant device of Absorbable Polydioxanone Suture with Needle is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2008

Foosin Medical Supplies, Inc.
% Shanghai Midlink Business
Consulting Co., Ltd.
Ms. Diana Hong
Suite 8D, Zhongxin Zhongshan Mansion
No. 19, Lane 999, Zhong Shan No. 2 Road(S)
Shanghai, China 200030

Re: K073614
Trade/Device Name: WG-Surgical Sutures with Needle
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: II
Product Code: NEW, GAM
Dated: April 4, 2008
Received: April 4, 2008

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K073614

Device Name: WG-Surgical Sutures with Needle

Indications for Use:

Absorbable polyglycolic acid suture with needle is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic, cardiovascular and neurological tissues.

Absorbable Polydioxanone Suture with Needle is indicated for use in all types of soft tissue approximation, including use in cardiovascular tissue where growth is expected to occur, PDO suture is not indicated in adult cardiovascular tissue, microsurgery, ophthalmic and neural tissue.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073614